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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/646,043 | 10/25/2000 | Eino Elias Hakalehto | 933-162P | 3800 |

2292 7590 01/15/2004

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| EXAMINER |
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SHAHNAN SHAH, KHATOL S

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| ART UNIT | PAPER NUMBER |
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1645

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/646,043

Applicant(s)

HAKALEHTO, EINO ELIAS

Examiner

Khatol S Shahnan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/08/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17, 19, 20, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17, 19, 20, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment and response received 10/08/2003, are acknowledged. Claims 21 and 24-26 were canceled. Claims 14, 15, 16, 17, 19, 20 and 22 were amended.
2. Applicant's supplemental response and declaration under 37 C.F.R. 1.132 received 10/23/2003, are acknowledged.
3. Currently claims 14-17 and 19, 20, 22 and 23 are pending and under consideration.

Prior Citations of Title 35 Sections

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

5. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 has been submitted with this office action.

Rejections Moot

6. Rejection of claims 21 and 24-26 made under 35 USC 112-first paragraph in paragraph 14 of the office action mailed 4/09/2003 is moot in view of applicant's cancellation of the claims.
7. Rejection of claims 21 and 24-26 made under 35 USC 103(a) in paragraphs 16 of the office action mailed 4/09/2003 is moot in view of applicant's cancellation of the claims.

Rejections Withdrawn

8. Rejection of claims 14-17 and 19, 20, 22 and 23 under 35 U.S.C. 112, first paragraph made in paragraph 14 of the office action mailed 4/09/2003 is withdrawn in view of applicant's amendments and declaration.
9. Rejection of claims 14-17 and 19, 20, 22 and 23 under 35 U.S.C. 112, second paragraph made in paragraph 15 of the office action mailed 4/09/2003 is withdrawn in view of applicant's amendments.

Rejections Maintained

10. Rejection of claims 14-17 and 19, 20, 22 and 23 under 35 U.S.C. 103, made in paragraph 16 of the office action mailed 4/09/2003 is maintained.

The rejection was as stated below:

Claims 14-17 and 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thorns, C. J. et al. (US Patent Number 5,510,241) prior art already made of record, in view of Blackburn, C. de W. (Journal of Applied Bacteriology, Vol. 75, pp. 199-214, 1993).

Claims as amended now recite a method for detecting bacteria having fimbriae, comprising detecting bacteria having fimbriae from a cultivation medium within the time period of 3 to 10 hours from the onset of cultivation, by detecting fimbrial antigens, which are, expressed soon after inoculation into the medium.

Thorn et al. teach a method for detecting for the presence of *Salmonella* species expressing fimbrial antigens, which have been grown on a selected medium. (see title and abstract and claims). Thorn et al. used a variety of liquid and solid media (see column 2, lines 25-65) and various temperature ranges from 22°C to 60° C (see columns 5 and 6). Thorn et al. teach

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detecting bacteria having fimbriae from a cultivation medium within the time period of 18 hours from the onset of cultivation (see column 7, example I). Thorn et al. also used direct binding and indirect ELISA methods. Thorn et al. further teach a method wherein the microbial antigens are detected with antibodies, which have been produced against synthetic peptides or a derivative thereof (see column 11 and claims). Thorn et al. also teach derivatives of the claimed synthetic peptide (see SEQ ID # 1, (i.e. amino acid 165-167) columns 26-28). Thorn et al. fails to teach time period of 3 to 10 hours from the onset of cultivation

However, attempts to reduce the incubation periods of either pre-enrichment or selective enrichment to 6- 8 hours for rapid methods of detection is routine in the art of microbiology (see Blackburn, page 199, Rapid Cultural Techniques).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the rapid method of screening taught by and the method taught by Thorn et al. to obtain the instant disclosure. Given the fact that rapid screening methods for bacteria such as *Salmonella* are needed. One having ordinary skill in the art would have been motivated by expectation of success and the attainment of a better method to obtain a method which shortens the cultivation period for detecting bacteria such as *Salmonella* which are a major cause of food poisoning. New approaches should be rapid, so that results can be obtained and appropriate action can be taken within a shorter period.

Applicant's arguments filed 10/08/2003 have been fully considered and are not persuasive. Applicant argues " that Thorns discloses a method of testing for the presence of *Salmonella* by detecting antibodies to *Salmonella*. Thorns fails to disclose or suggest a fast assay where the presence of *Salmonella* is detectable within 3 to 10 hours as with the present invention".

Applicant further argues, “ Blackburn is primarily concerned with the shortening the length of cultural enrichment”.

It is the examiner’s position it seems the applicant argues against the references individually. It is also the examiner’s position that Thorn et al. teach a method for detecting the presence of *Salmonella* species expressing fimbrial antigens as stated in the rejection above. The references in combination teach the claimed invention. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

11. No claims are allowed.

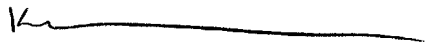
12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.




Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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January 09, 2004



RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER